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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,455	01/15/2004	Charles O. Townley	THUMB-604DIV	5634
7590 Christopher John Rudy 209 Huron Ave., Ste. 8 Port Huron, MI 48060		08/02/2007	EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/758,455

Applicant(s)

TOWNLEY, CHARLES O.

Examiner

Brian E. Pellegrino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 April 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 and 39 is/are allowed.
- 6) ☒ Claim(s) 21-26, 28, 29, 31, 32, 34-37 and 40-42 is/are rejected.
- 7) ☒ Claim(s) 27, 30 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION***Response to Amendment***

The declaration under 37 CFR 1.132 filed 4/17/07 of which is a copy of a declaration filed 3/19/01 to parent application 09/352472 is insufficient to overcome the rejection of claims 21-26,28,29,31,32,34-37,40-42 based upon the teachings of Townley (2934065), Abouaf et al. (5871547) as applied in the last Office and used for their teachings in the current action because: anybody of ordinary skill in the art would clearly look to other joint implants for teachings of stem structure to implant in bone canals. First it should be noted that the US classification system for class 623 has a broad category of joint implants 18.11 of which when further defined or categorized is broken down into all the different joints as subclasses under the broad joint implant subclass of 18.11. Secondly, for a sample of what one of ordinary skill in the art would consider relevant and search see the list of patents for thumbs and fingers as mentioned below in the arguments. These patents all listed other joint subclasses that were searched and argued as being non-analogous. Thus the Examiner is not persuaded by the opinion of Mr. Rudy or Mr. Pringles declaration.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21,22,25,26,28,29,40,41 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin (5507818). Fig. 1 shows a modular joint prosthesis having a stem **13** and a head **12** attached to the stem. As seen in the drawing the angle of projection of the stem from the head is acute. Fig. 3 illustrates an eccentric attachment of the head to the stem. McLaughlin's eccentric attachment includes a middle wedge shaped connector **11** having an angled receptacle **22** for a trunion that can be construed as eccentric and offset from the center of the generally planar end of the head. Fig. 3 also illustrates the head **12** having a generally hemispherical articulating surface and an abrupt planar end with a trunion receiving cup **22**. It can also be seen that the stem **13** has a trunion **21**. McLaughlin does disclose the prosthesis can be used for any joint by preparing two articulating surfaces to receive the implant, col. 1, lines 26-28 and is not limited to that listed (col. 2, lines 1,2). However, McLaughlin fails to explicitly disclose the joint of repair is the thumb. It would have been obvious to one of ordinary skill in the art to use a head of a size for a correspondingly prepared trapezium bone stock and a stem of a size for intramedullary insertion in metacarpal bone stock for the implant of McLaughlin since one of ordinary skill in the art would understand that the body is made up of many joints and that when the thumb joint has been injured or diseased it would be desirable to replace with a prosthesis.

Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin '818 in view of Townley (2934065). McLaughlin is explained supra. However, McLaughlin fails to disclose the flanged stem profile. Townley teaches (Fig. 3) a stem having a tri-flange cross-section. Townley also teaches this is to preserve bone

structure and prevents rotation of the stem in the bone, col. 4, lines 60-63. It would have been obvious to one of ordinary skill in the art to use the triflange stem profile as taught by Townley with the prosthesis of McLaughlin to better secure the stem in the bone canal such that it does not move while in the patient.

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin '818 in view of Lane et al. (5674297). McLaughlin is explained supra. However, McLaughlin fails to disclose an inwardly curved stem. Lane teaches (Figs. 4,7) a stem 52 having an inward curve. It is well known in the art that the curvature of a prosthetic stem is to match the curvature of the bone. It would have been obvious to one of ordinary skill in the art to use the inward curve profile as taught by Lane et al. for the stem of McLaughlin to better match the contour of the bone canal such that it does not cause any uneven stress distribution to cause an unwanted fracture.

Claims 31,32,34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin '818 in view of Abouaf et al. (5871547). McLaughlin is explained supra. However, McLaughlin fails to disclose the head is ceramic or to utilize a Morse taper to couple the head and stem. Abouaf et al. teach (Fig. 1) a modular prosthesis having a stem with a trunion that is tapered and a head with a receptacle that is tapered to match the trunion. Abouaf also teaches to utilize different materials, such as ceramic for articulating heads of joints because of its toughness, col. 4, lines 7,29-31,38-42. Abouaf additionally discloses the implant can have a metal stem and ceramic head (col. 6, lines 44-51) that are assembled via the Morse taper. It would have been obvious to one of ordinary skill in the art to utilize a ceramic head and an alternative coupling, such

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as a Morse taper for the trunion of the metal stem as taught (col. 3, lines 61, 63, 65) by Abouaf et al. with the thumb implant of McLaughlin such that the prosthesis has reduced wear at the joint or articulating area and provides an easy coupling to match the trunion and cup.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin '818 in view of Wright Medical Technology. McLaughlin is explained supra. However, McLaughlin fails to disclose a head having a diameter of 13mm-19mm. The Swanson thumb implant can have a head with a diameter greater than 13mm, page 2. It would have been obvious to one of ordinary skill in the art to use a head having a diameter greater than 13mm as taught by Wright Medical Technology with the prosthesis of McLaughlin such that it properly fits the patient's anatomical dimensions.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over McLaughlin '818 in view of (ASTM, 1998). McLaughlin is explained supra. However, McLaughlin fails to disclose a porous coating on the prosthesis. The ASTM teaches that porous coatings can be applied on prostheses to improve tissue attachment and also bonding of cements to the prostheses, p. 700. It would have been obvious to one of ordinary skill in the art to incorporate a porous coating on the prosthesis of McLaughlin such that it enhances the securement of the prosthesis in the implanted site as taught by the ASTM.

Allowable Subject Matter

Claims 38,39 are allowed.

Claims 27,30,33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

However, if claim 27 is amended to be in independent form,

Claim 27 will be objected to under 37 CFR 1.75 as being a substantial duplicate of claim 38. When two claims in an application are duplicates or else are so close in content that they both *cover the same thing*, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Response to Arguments

Applicant's arguments filed 4/17/07 have been fully considered but they are not persuasive. Applicant argues that the McLaughlin implant was not positively disclosed for a thumb. The Examiner would like to note that as mentioned above, McLaughlin stated the prosthesis was not limited to that mentioned in the patent, col. 2, lines 1,2. As is well known to one of ordinary skill in the art, the human body is made of many joints and one of ordinary skill in the art would have considered the thumb joint as a site of repair that is in need of replacement. Regarding Applicant's representatives comments that the Abouaf reference teachings cannot be combined with a thumb implant is mistaken. The Examiner would like to make the Applicant's representative

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aware of numerous references to thumb and finger implants of where one of ordinary skill searched all joints that included hips, shoulders, fingers, knees, etc. See for example US patents 5405399, 5007932, 5702469, 5507818, 4955916, 4944758, 5011497, 5326364, 5645605, 5507822. Thus, the Abouaf reference is relevant and analogous art and its teachings can be combined with thumb implants.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (7:30am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

Brian E. Pellegrino